U.S. Environmental Protection Agency
Science Advisory Board
Metals Assessment Panel
Final Minutes of Public Conference Call Meeting August 29, 2002

Committee: Metals Assessment Panel of the U.S. Environmental Protection Agency's Science Advisory Board (SAB). (See attached Roster)

Date and Time: August 29, 2002 from 2-4 Eastern Time (See attached Federal Register Notice)

Location: Science Advisory Board, Room 6013, Ariel Rios North, 1200 Pennsylvania Ave, Washington D.C.

Purpose: Three conference call meetings, including this one, were announced in 67 FEDERAL REGISTER, Number 46505-46506, July 15, 2002. The purpose of this public teleconference meeting is to: (a) Allow panelists to identify points they think should be addressed in the Panel's report; (b) provide other panelists with an opportunity to add to or correct those points; and (c) identify for the Agency and the Public any areas where the panel would welcome additional information or comment.

Materials Available: In addition to materials provided before or at the August 15, 2002 conference call of the panel, the panel received:

1. the agenda for the meeting
2. the collected preliminary comments of individuals on the SAB Metals Assessment Panel, distributed on August 28.

NOTE: The review materials are all posted at the Risk Assessment Forum Website (http://cfpub.epa.gov/ncea/raf/rafpub/cfm?ActType=default). They include the draft Metals Action Plan, five public comments on the Action Plan, and the summary of a meeting held February 20, 2002. As of August 15, 2002, the SAB itself has received no additional written public comments for the review.

The announcements for the meetings, agendas, hand-outs distributed at the meetings, and biosketches for the panelists can be found at the Science Advisory Board's website (http://www.epa.gov/sab/metalspanel.html)

Attendees:

Present on the Phone:

Panel: Drs: Thomas, Costa, Friedland, Fowler, Hayes, O'Rourke, Pittinger, Tran, Weis, Windom. (This is the full panel)
(Affiliations can be found on the attached roster)

EPA: Ann Fairbrother, Kevin Minoli, Dave Mount, Marc Stifelman, Steve DeVito

Public: Rob Reash, Neil Shah, Bill Allen, Leonard Levin, Ann Smith-Reiser, Bill Adams

Present in the Room:

SAB Staff: Kathleen White, Zisa Lubarov-Walton

EPA Staff: Keith Sappington ORD/NCEA, Randy Wentsel ORD, Bob Jones OPPT, Charles Delos OW/OST, Bill Wood (ORD/NCEA/IO)

Federal: Kevin Bromberg of SBA

Public: Jane Luxton of King and Spalding and John Arnett of the Copper and Brass Manufacturer's Council

Summary

At this meeting the panelists presented their individual responses to the various charge questions, focusing on the questions where they were assigned, but not confined to those questions. The meeting went in the order of the agenda, but the oral summaries took longer than planned leaving very little time for other agenda items.

A more chronological summary follows.

SAB staff asked whether anyone objected to being taped so that we could practice. Those present agreed to be taped.

The chair noted this call provided the panel with an opportunity to explore ideas about the review and identify major issues. Because no one will be held to any comments made today, it is a great opportunity to try out different ideas to make sure the Panel doesn't miss anything. The panel can make lots of changes before next meeting.

The panelists responded to each charge question. Although some questions were taken out of order at the conference call, they appear in the attachment in numerical order. The minutes will not attempt to summarize the panelists' oral comments by charge questions because these closely tracked their attached written comments.

At 3:20, the chair asked the panelists if they had any more key ideas.

Mary Kay O'Rourke spoke of her soil and plant interaction work in Mexico. She observed that there is a line in the action plan assuming bioasorption through plants is assumed. This assumption throws out a lot of knowledge of soils, plant associations, and human use of plants. It is a mistake to exempt plants from this discussion.

Herb Windom agreed because plants can be the main pathway from the marine ecosystem to the land. Plants are very important in determining how metals get into the food chain.

Charlie Pittinger thought ranking should be done in the context of exposure.

At 3:30 the chair proposed the following summary of what she had heard the Panel say.

> Either EPA is doing too much in one document
> or
> it could reorganize
> or
> do test cases before finishing it
> or
> EPA should do more.

These sound like major changes to her.

Is that the sense of the group? Is there disagreement within the group about the extent of change needed?

Bernie Weiss raised the issue again of who the audience is.

Andy Friedland was puzzled. He heard what the chair did, but inferred that it indicates the Panel is all over the place. Thomas noted many panelists said the Action Plan was too general. Therefore, those different changes were all ways to address the general comment that the Action Plan is too general. In contrast, she thought that at the beginning of the call Dr. Fowler had said that these were the right issues and the Action Plan is generally on the right track and just needs some more detail.

Herb Windom was not sure the right issues are there. Perhaps persistence is not an issue and speciation is exaggerated. The Action Plan assumes we can jump further ahead than we really can. He returned to SAB's report on Integrated Environmental Decision-Making (IED). The Action Plan needs to provide a mechanism for making the decisions about metals in the environment instead of making one guidance for all metals. The decision tree approach is a very logical approach. Kim Hayes said we are looking at risk assessment, which is a systematic analytical approach to examining adverse effects. It is a very well defined and approach (hazard assessment followed by exposure) which seemed more logical to him than the tiered regulatory approach. Whether we have the data an the state of science to push it to the mechanistic level are important questions. The risk-based approach is what the framework ought to look at it.

Max Costa said that this could be solved by taking each metal individually -- or perhaps in small groups. Andy Friedland echoed Weis's comment that we are trying to get from a novel to a screenplay. He favored streamlining the document so it helps with IED and comes to a point rather than becoming encyclopedic.

At 3:30 the chair provided an opportunity for Agency comment. Bill Wood welcomed comments from the technical panel, noting he was confused by some of the discussion. The Action Plan will be of historical interest, but it will not be how EPA does risk assessments, it should identify what is different about metals so risk assessors can attend to it. EPA's primary concern is, "Was anything left out?"

Two months from now they will be working on the framework and guidance, not revising the Action Plan.

Likewise -- their focus is, "what is different about metals?" From that standpoint they are not interested in bioethics, subpopulations, and other issues that apply more broadly to risk assessment.

Randy Wentsel thanked panel, then asked about speciation and environmental chemistry. After observing that the Panel seems to think speciation is not important, he asked whether they would say the same about environmental chemistry. He thought EPA would value ideas on the framework, whether to simplify or look at it from the risk assessor's standpoint

Windom agreed that environmental chemistry is the right term, saying we do want to understand environmental chemistry of metals. We don't know as much about speciation. O'Rourke thinks this is true for water, but might not be for other media, especially if you are considering methylation. Windom says that's his point. We know more about mercury and have tools to look at it; we don't have the same tools and understanding for other metals. Environmental chemistry is the more comprehensive term.

Steve De Vito said EPA envisioned the Framework as an articulation of principles, not an encyclopedia. The intent of the framework was to set out the fundamental principles of what has to be considered when you evaluate metals whether it is site-specific or at the national level. It sounded to him as though considering synergisms would be difficult. He asked how much is known about the synergy of toxicity among metals and what is the state of science?

Bernie Weiss responded that there is an enormous amount of information on combinations of metals in the nutrition literature about how a dose of one changes the action of the others. Another panelists was less sanguine about the applicability of the nutrition literature, noting that the nutritionists are not too fussy about their experiments.

DeVito asked, "How would you apply this to estimate cumulative affect at a Superfund Site?" Some metals might compete with each other, some might add. But state of

science is not very far advanced

Bruce Fowler noted that ATSDR is having a meeting on mixtures during the Panel meeting. He referred to the International Conference on Chemical Mixtures being held September 10-12, 2002 in Atlanta. The Agency for Toxic Substances and Disease Registry of the Department of Health and Human Services is the sponsor and organizer; FDA, EPA, NIEHS, NIOSH are cosponsors with the Health Council of the Netherlands, the International Joint Commission, and the Society of Toxicology. The conference website is www.atsdr.cdc.gov/iccm.html.

Fowler noted that it is difficult, but not impossible and the data base is not large. It will get larger in the near future.

Dave Mount didn't argue with the expertise of the Panel on the issues or their ability to bring the Agency out to the edge of the understanding of metals. He himself is a science advisor to people who develop regulatory programs and noted that, in some ways, it is easier to do a detailed assessment than one that is less detailed. Making a decision about a Superfund site is one thing, TRI reporting levels is another. The latter brings in a whole different way of thinking about a list of metals. This will come into play in the Framework more than in the Action Plan. The issues are not always what are the fine details, but sometimes, in what are the simplifications.

Thomas returned to Wood's comment about the panel mis-interpreting the purpose of the Action Plan and asked whether the panel would like to talk this over. Weiss was concerned about the degree of coordination between the Framework and the Guidance.

At 3:45 Kevin Bromberg of SBA mentioned the process EPA used to develop the basis for a Framework document to help EPA think through the process, how issues related to one another, and what methods could be used. This led to the Ecological Risk Assessment Guidelines.

Wood didn't think EPA can say now what the Guidance will look like until they go through the Framework.

At 3:50 the chair offered an opportunity for brief public comment, however, given the brief time remaining, no one from the public wanted to say anything.

The Chair then said that the Panel wants to finish the report September 10-12. Panelists want to come prepared, but will not do the review until September 10. She asked panelists to revise their responses to the questions. Panelists will work through the lead authors, sending copies to the DFO. Thomas will draft a summary. She would like references because they help resolve the issue within the panel of whether something is scientifically sound. Because the Panel is trying to finish by the 12th it would be good to circulate revised written material in advance. To this end, panelists should have their revisions to the DFO the Thursday before the meeting.

Dr. Thomas adjourned the meeting at 4:00

Respectfully Submitted: Certified as True:

/ Signed / ***/ Signed /***

Ms. Kathleen Conway
Designated Federal Official
Environmental Engineering Committee

Dr. Valerie Thomas, Chair
Metals Assessment Panel

Electronic Attachments

1. Federal Register notice
2. Agenda for the meeting
3. Committee roster
4. Preliminary Comments of Individual Panelists

Attachment 1: Federal Register Notice

EPA Science Advisory Board, Notification of Public Advisory Committee Meetings; Metals Assessment Panel

[Federal Register: July 15, 2002 (Volume 67, Number 135)]
[Notices]
[Page 46505-46506]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr15jy02-60]

ENVIRONMENTAL PROTECTION AGENCY [FRL-7245-4]

EPA Science Advisory Board, Notification of Public Advisory Committee Meetings; Metals Assessment Panel

Pursuant to the Federal Advisory Committee Act, Public Law 92-463, notice is hereby given of three conference call meetings of Metals Assessment Panel of the US EPA Science Advisory Board (SAB). These conference call meetings are preparatory for a face-to-face meeting to be held September 10-12 in or near Washington DC. Once the location is known, the face-to-face meeting will be the subject of a separate announcement. The Panel will hold conference calls on the dates and times noted below. All times noted are Eastern Time. All meetings are open to the public, however, seating is limited and available on a first come basis. For teleconference meetings, available lines may also be limited.

Important Notice: Documents that are the subject of SAB reviews are normally available from the originating EPA office and are not available from the SAB Office--information concerning availability of documents from the relevant Program Office is included below.

Background

The EPA Science Advisory Board (SAB, Board) announced in 67 FR 38957-38959, June 6, 2002 that it had been asked to undertake a review of EPA's draft Action Plan for the ``Framework for Metals Assessment and Cross-Agency Guidance for Assessing Metals-Related Hazard and Risk.'' The background, charge, and description of the review documents appear in the above referenced Federal Register notice and are also available at the SAB website (www.epa.gov/sab). The notice also included a call for nominations for members of the panel in certain technical expertise areas needed to address the charge and described the process to be used in forming the panel. A Short List of individuals from which the panel will be chosen has been posted at the SAB's website.

The following three teleconference meetings will be hosted out of Conference Room 6013, USEPA, Ariel Rios Building North, 1200 Pennsylvania Avenue, NW, Washington,

DC 20004. The meetings are all open to the public, but, due to limited space, seating will be on a first-come basis. The SAB Staff encourages members of the public who plan to attend any or all of the three meetings in person to call a few days in advance of that meeting and to arrive at least 15 minutes before the scheduled start time so that the necessary building security requirements can be accommodated before the start of the meeting. The public may also attend the teleconference meetings via telephone, however, lines may be limited. For further information concerning the meetings or how to obtain the teleconference phone number, please contact the individuals listed at the end of this FR notice.

1. Metals Assessment Panel--August 8, 2002 Teleconference

The Metals Assessment Panel will meet on August 8, 2002 by teleconference from 2 p.m. to 4 p.m. Eastern Time.

Purpose of the Meeting--The purpose of this public teleconference meeting is to: (a) Discuss the charge and review materials provided to the Metals Assessment Panel; (b) to clarify any questions relating to the charge and the review materials; (c) to discuss specific charge assignments to the panelists; and (d) to clarify specific points of interest raised by the Panelists in preparation for the face-to-face meeting to be held on September 10-12, 2002.

See below for availability of review materials, the charge to the review panel, and contact information.

2. Metals Assessment Panel--August 15, 2002 Teleconference

The Metals Assessment Panel will meet on August 15, 2002 by teleconference from 2 p.m. to 4 p.m. Eastern Time. Purpose of the Meeting--The purpose of this public teleconference meeting is to: (a) Hear invited presentations; (b) to hear public comment; (c) to provide an opportunity for panel discussion; and (d) to identify areas where the Panel would welcome additional input.

See below for availability of review materials, the charge to the review panel, and contact information.

3. Metals Assessment Panel--August 29, 2002 Teleconference

The Metals Assessment Panel will meet on August 29, 2002 by teleconference from 2 p.m. to 4 p.m. Eastern Time.

Purpose of the Meeting--The purpose of this public teleconference meeting is to: (a) Allow panelists to identify points they think should be addressed in the Panel's report; (b) provide other panelists with an opportunity to add to or correct those points; and (c) identify for the Agency and the Public any areas where the panel would welcome additional information or comment.

See below for availability of review materials, the charge to the review panel, and contact information.

FOR FURTHER INFORMATION CONTACT: Persons desiring information about public participation in the meetings identified above must contact Kathleen White, Designated Federal Officer, Metals Assessment Panel, USEPA Science Advisory Board (1400A), Suite 6450Z, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone/voice mail at (202) 564-4559; fax at (202) 501-0582; or via e-mail at white.kathleen@epa.gov.

Requests for oral comments must be made in writing (e-mail, fax or mail) and received by Ms. White no later than noon Eastern Time on the following dates: for the August 8 teleconference call, requests must be received by August 1st; for the August 15 teleconference call, requests must be received by August 8; for the August 29 conference call, requests must be received by August 22.

The public is encouraged to provide written comments. Those who prefer to provide oral comments are encouraged to schedule them for August 15. The oral public comment period will be limited and divided among the speakers who register. Additional opportunities for public comment will be available at the face to face meeting to be held September 10-12. Registration is on a first come basis. Speakers who have been granted time on the agenda may not yield their time to other speakers. Speakers who are unable to register in time may provide their comments in writing.

Members of the public desiring additional information about the meeting locations or the call-in number for the teleconference before June 30, 2002, must contact Ms.Zisa Lubarov-Walton, Management Assistant, EPA

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Science Advisory Board (1400A), Suite 6450N, U.S. EPA, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone/voice mail at (202) 564-4537; fax at (202) 501-0582; or via e-mail at lubarov-walton.zisa@epa.gov

A copy of the draft agenda for each meeting will be posted on the SAB Website (www.epa.gov/sab) (under the AGENDAS subheading) approximately 10 days before that meeting.

Availability of Review Material--There is one primary document that is the subject of the review. The draft Metals Action Plan is available on the EPA Risk Assessment Forum's website: http://www.epa.gov/ncea/raf/rafpub.htm. The review document is also available electronically at the following site http://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=4580 For questions and information pertaining to the review documents, please contact Dr. Bill Wood (Mail Code 8601D), U.S. Environmental Protection Agency, Washington, DC 20460; tel. (202) 564-3358, e-mail: wood.bill@epa.gov. Dr. Wood will refer you to the appropriate contact for the particular issue of interest.

Providing Oral or Written Comments at SAB Meetings

It is the policy of the EPA Science Advisory Board to accept written public comments of any length, and to accommodate oral public comments whenever possible. The EPA Science Advisory Board expects that public statements presented at its meetings will not be repetitive of previously submitted oral or written statements.

Oral Comments: In general, each individual or group requesting an oral presentation at a face-to-face meeting will be limited to a total time of ten minutes (unless otherwise indicated). For teleconference meetings, opportunities for oral comment will usually be limited to no more than three minutes per speaker and no more than fifteen minutes total. Deadlines for getting on the public speaker list for a meeting are given above. Speakers should bring at least 35 copies of their comments and presentation slides for distribution to the reviewers and public at the meeting.

Written Comments: Although the SAB accepts written comments until the date of the meeting (unless otherwise stated), written comments should be received in the SAB Staff Office at least one week prior to the meeting date so that the comments may be made available to the review panel for their consideration. Comments should be supplied to the appropriate DFO at the address/contact information noted above in the following formats: one hard copy with original signature, and one electronic copy via e-mail (acceptable file format: Adobe Acrobat, WordPerfect, Word, or Rich Text files (in IBM-PC/Windows 95/98 format). Those providing written comments and who attend the meeting are also asked to bring 35 copies of their comments for public distribution.

Meeting Access--Individuals requiring special accommodation at this meeting, including wheelchair access to the conference room, should contact Ms. White at least five business days prior to the meeting so that appropriate arrangements can be made.

General Information--Additional information concerning the Science Advisory Board, its structure, function, and composition, may be found on the SAB Website (http://www.epa.gov/sab) and in the Science Advisory Board FY2001 Annual Staff Report which is available from the SAB Publications Staff at (202) 564-4533 or via fax at (202) 501-0256.

Dated: July 9, 2002.
Robert Flaak,
Acting Deputy Director, EPA Science Advisory Board.
[FR Doc. 02-17691 Filed 7-12-02; 8:45 am]
BILLING CODE 6560-50-P

Attachment 2 Agenda

SCIENCE ADVISORY BOARD - METALS ASSESSMENT PANEL
CONFERENCE CALL MEETING
August 29, 2002
Room 6013 Ariel Rios Building, 1200 Pennsylvania Avenue NW
Washington DC
Final Agenda of August 26

2:00	Mechanics of Call, Calling the Roll	Kathleen White, DFO
2:05	Opening Remarks	Valerie Thomas, Chair

(NOTE: These are out of numerical due to a scheduling problem of one of the panelists.)

2:10 Preliminary Individual Responses to Charge Question #1
Fowler, Pittinger, O'Rourke, Windom, Other Panelists

2:20 Preliminary Individual Responses to Charge Question #2
Costa, Hayes, Friedland, Windom, Other Panelists

2:30 Preliminary Individual Responses to Charge Question #4
O'Rourke, Tran, Other Panelists

2:40 Preliminary Individual Responses to Charge Question #5
Tran, Fowler, Other Panelists

2:50 Preliminary Individual Responses to Charge Question #3
Hayes, Windom, Other Panelists

3:00 Preliminary Individual Responses to Charge Question #6
Weiss, Windom, Other Panelists

3:10 Preliminary Individual Responses to Charge Question #7
Pittinger, Costa, Other Panelists

3:20 Preliminary Individual Responses to Charge Question #8
Friedland, Weiss, Other Panelists

3:30 Additional Comments by Panelists and Panel Discussion
(It may be that not all panelists will be able to express their thoughts in the ten minutes scheduled per question)

3:45 Brief Opportunity for Comment by Agency and Public

3:50 Summary and Instructions
4:00 Adjourn

Attachment 3 Roster

U.S. Environmental Protection Agency
Science Advisory Board
Executive Committee
Metals Assessment Panel*

CHAIR

Dr. Valerie Thomas, Research Scientist, , Princeton Environmental Institute, Princeton, NJ
Also Member: Environmental Engineering Committee

OTHER SAB MEMBERS

Dr. Charles A. Pittinger, Director of Environmental Research and Program Manager, SoBran, Incorporated, Cincinnati, OH
Member: Ecological Processes and Effects Committee

CONSULTANTS

Dr. Max Costa, Professor and Chairman, Department of Environmental Medicine, School of Medicine, New York University, New York, NY

Dr. Bruce Fowler, Professor of Epidemiology and Toxicology, University of Maryland Program in Toxicology, University of Maryland , Baltimore, MD

Dr. Andrew Friedland, Professor, Environmental Studies Program, Dartmouth College, Hanover, NH

Dr. Kim Hayes, Associate Professor of Environmental Engineering, Department of Civil and Environmental Engineering, University of Michigan, Ann Arbor, MI

Dr. Mary Kay O'Rourke, Associate Professor of Public Health Research & Medicine, College of Public Health, University of Arizona, ,

Dr. Nga L. Tran, Senior Managing Scientist, Exponent, Washington, DC

Dr. Bernard Weiss, Professor, Department of Environmental Medicine, University of Rochester Medical Center, Rochester, NY

Dr. Herbert L. Windom, Professor, Skidaway Institute of Oceanography, Savannah, GA

SCIENCE ADVISORY BOARD STAFF

Ms. Kathleen White, Designated Federal Officer, US EPA Science Advisory Board (1400A), 1200 Pennsylvania Avenue, NW, Washington, DC,

Ms. Zisa Lubarov-Walton, Management Assistant, US EPA Science Advisory Board (1400A), 1200 Pennsylvania Avenue, NW, Washington, DC,

* Members of this SAB Panel consist of

a. SAB Members: Experts appointed by the Administrator to serve on one of the SAB Standing Committees.

b. SAB Consultants: Experts appointed by the SAB Staff Director to a one-year term to serve on ad hoc Panels formed to address a particular issue.

c. Liaisons: Members of other Federal Advisory Committees who are not Members or Consultants of the Board.

d. Federal Experts: The SAB charter precludes Federal employees from being Members of the Board. "Federal Experts" are federal employees who have technical knowledge and expertise relevant to the subject matter under review or study by a particular panel.

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Attachment 4

Collected Preliminary Comments

of Individuals on

the SAB Metals Assessment Panel

Distributed mid-day on August 28

for

Conference Call

August 29, 2002

CHARGE QUESTION # 1

1. Please comment on the soundness of the proposed organizing principles suggested by the public that are reflected in the draft Action Plan for the ``Framework for Metals Assessment and Cross-Agency Guidance for Assessing Metals-Related Hazard and Risk." (The proposed organizing principles, listed in section 1 of the draft Action Plan, include the following: providing a basis for identifying and prioritizing among metals, metal alloys and other metal compounds with respect to hazard and risk, use of sound science, use of a tiered approach, recognition of the influence of bioavailability on toxicity, and initially focus on hazard assessment as a screening tool.)

Fowler

In general, the organizing principles suggested in the Draft Action Plan for metals are broad but generally sound and address a number of issues that should be included in a long term EPA strategy.

Specifically, the plan for identifying and prioritizing metals, metal alloys and other metal compounds is critical with respect to assessment of hazard and risk. This process is important since metals/metalloids and compounds of these elements of greatest interest to public health or the environment will vary over time. There is hence the need for a flexible process that can accommodate these changing priorities.

The use of sound evidence, based upon state of the art science, is absolutely critical to the development of credible environmental regulations. These regulations need to take advantage of modern scientific tools which incorporate mechanistic data. While some of these methods will require validation with time and experience, inclusion of a narrative commentary on their potential application to regulatory approaches for metals /metalloids will enhance the utility of the overall plan over time. For example, as some of these newer methods (eg. biomarkers) are validated and prove useful, then they can be incorporated into future versions of the Action Plan. The application of new biochemical tools into the tiered approach strategy discussed on page 35 of the Draft. The inclusion of the such mechanistic data would integrate metal induced effects from the molecular to in vitro to in vivo studies. The use of such approaches would enhance the sensitivity a National Hazard/ Risk Assessment. This approach could ultimately lead to a mechanism-based regulatory process which will add scientific credibility to any derived regulations. As discussed in Question #5, the use of mechanistic will also provide assistance in dealing with the issue of metal mixtures which is a core issue for Superfund sites. Inclusion of mechanistic data in the discussed tiered approach could hence also be very useful in interpreting findings and predicting risk from such complex mixture situations.

There is clear evidence of the critical role that bioavailability exerts on toxicity for a number of metals/metalloids. In aqueous systems, factors such as salinity, complexation with humics and methylation by bacteria are examples of the processes

that will influence uptake/toxicity by organisms living in different environments. In terrestrial environments, complexation of toxic elements with respirable particles in soil may vary as a function of soil pH, and bacterial populations. Metal binding to respirable particles may also vary as a function incineration temperatures. The above are examples of common factors that will influence both bioavailability and toxic potential to receptor organisms. The document would be strengthened by a more detailed inclusion of such factors beyond that currently incorporated. The intracellular handling of metals/metalloids in target cell populations is a topic which is not addressed in the current Draft document beyond the paragraph on page 14 in relation to the toxic potential of metals to aquatic species. The potential role of these compartments as factors influencing the bioaccumulation of metals in some edible species should be further developed. There is a much larger literature on this subject in both mammals and aquatic species than in the cited references. A more complete discussion of this topic would strengthen the document. Cell membrane transporters for metal uptake, metal-binding proteins, methylation processes, inclusion bodies or concretions are all common mechanisms by which cells may regulate the intracellular bioavailability of toxic metal/metalloid species to other sensitive molecules in mammals and non-mammals. There is a relatively large database on these factors in the literature and this information could be incorporated with relatively little effort.

Finally, the initial focus on hazard assessment as a screening tool could also be strengthened by inclusion of at least 3 other factors. It must be remembered that dose is only one factor in assessing hazard. The duration of exposure is another critical variable that is well appreciated and essential for chronic low dose exposures which are more common than the acute exposures considered by Parcelsus. The issue of toxicity endpoints also needs to be developed in the document. Death, cancer, reproductive failure are clearly major endpoints which are readily observed. These endpoints are undoubtedly anteceded by cellular and molecular processes (eg. apoptosis) and should at least be discussed. The issue to hazardous to WHOM (eg. sensitive sub-populations) should also be addressed in more detail. Developmental life stages (eg trout fry), larvae of crustacea and the fetal/newborn in mammalian organisms are just a few examples of well-appreciated life stages in different species for which data exist. Susceptibility of geriatric populations are of increasing concern as the population of the U.S. and other countries ages. Release of bone stores of lead due to osteoporosis is an ongoing concern with regard to effects on the brain and kidney. The document and the use of hazard assessment as a screening tool would be strengthened by inclusion of a discussion of these important factors and more detailed discussion of populations at special risk.

Windom

<u>Metal vs. Metal Organic Compound</u>

It appears that the first tier in the Framework and Guidance documents should include consideration of whether the metal or a specific metal organic compound is the primary

concern. It is not clear that the approach being proposed is applicable to metal contamination across the board. An example is tributyltin (TBT). It's not tin we are concerned about, it's TBT, which is probably addressed better as an organic contaminant, where persistence is of concern and does apply much the same way as for organic contaminants. The more general approach to metals would appear to reflect a concern for the increase in environmental compartment such that levels of the toxic chemical species (e.g. methyl Hg) becomes important.

Insufficient Attention to Sediments

The approach appears to be centered on the aqueous phase (i.e. water quality). This may be because water quality standards serve as the guide. But sediments are the major environmental repository of metals and any framework and guidance must address concerns related to such things as natural versus anthropogenic enrichment of sediments and soils, stability of sediment bound metals, and natural attenuation of sediment contamination.

Hayes

The organizing principles suggested by the public and summarized in section 1 of the draft action plan are right on target and state the problems and issues of metal assessment. The bulleted items on page 5 provide an excellent organizing Framework and the relevant scientific issues to build the MAP document around. That being said, it may be worthwhile to review the scientific items listed on page 5 and insure that each can be mapped to a targeted summary issue as presented in Section 2. My sense was the MAP Draft Framework reflects some of the issues more directly than others but all are covered to a certain extent.

The major scientific issues suggested by the Public are stated below. Comments on each indicate my assessment of how well and where they are incorporated in the MAP.

Criteria and models properly incorporated into the Framework should reflect the critical importance of speciation, transformation, and bioavailabilty.

The incorporation of speciation and bioavailability in the Framework plan is clear through the inclusion of separate sections on speciation and bioavailability as areas were information is needed to improve the Agency's ability to assess risk and hazard of metals in the MAP. Transformation issues are largely dealt with in the MAP through the discussion of speciation, bioavailability, and persistence in the MAP. However, discussion of how criteria and models will incorporate these issues is not generally stated but that these issues should be considered is indicated in the MAP. Summary Issue 2.1.1, 2.1.2, and 2.1.3 point to the importance of including speciation in metals assessment in models and criteria. Similarly Summary Issues 2.2.1 - 2.2.4 address the need for incorporating biovailability into the metals assessment framework. Less directly related to targeted Summary Issues in the MAP is the incorporation of

transformation issues, although one could argue that Summary Issues related to persistence, bioavailability, and speciation must naturally address this issue. In order to establish which species predominates at a given time, or how long a species remains in a given form or under what conditions or changes in conditions a species is bioavailable, bioaccumulates, or is toxic, transformation issues must naturally be considered. The Summary Issues that indirectly address the issue of transformation and rates are Summary Issues 2.1.1 and 2.1.2 (in the speciation section), 2.2.1 and 2.2.3 (in the bioavailability section), 2.3.3 (in the bioaccumulation section), 2..4.1 (in the persistence section) and 2.5.1 (in the toxicity section).

Valid approaches for assessing persistence should be incorporate.

The section on persistence in the MAP does a reasonable job of addressing the major differences between persistence issues for organic compounds compared metals. In the case of metals, persistence issues should be considered in the context of both positive and negative aspects since persistence of metals in some forms are protective compared to other forms that are more mobile, bioavailable and toxic. This may be what is suggested by the use of "valid approaches for assessing persistence." Summary Issue 2.4.1 covers this need.

Alternative approaches for assessing bioaccumulation should be considered.

The section on bioaccumulation does a good job of pointing out the limitations of the bioaccumulation approaches for metals in comparison to organics. The Summary Issues 2.3.1 – 2.3.5 specifically consider the issues that need to be evaluated for utilizing current bioaccumulation measures (or not) for metal risk and hazard assessment.

Determine what is considered significant bioaccumulation of metals in human beings.

The section on bioaccumulation provides some information on the issues related to measuring bioaccumulation, in general, for metals, and the difficulties in establishing appropriate protocols for humans. The section in the MAP entitled "Assessing Hazard from Bioaccumulation in Terrestrial Organisms and the corresponding Summary Issue 2.3.3 address this issue.

Differentiate between substances and elements.

This importance of this issue is covered specifically in the section on speciation and indirectly in the other sections where speciation is considered in the context of bioavailability, bioaccumulation, persistence and toxicity. Specific Summary Issue where this is stated as important include Summary Issues 2.1.1 – 2.1.3 (in the speciation section), 2.2.1, 2.2.3, 2.2.4 (in the bioavailability section), 2.4.1 (in the persistence section), and 2.5.1 and 2.5.2 (in the toxicity section).

Thomas

The justification for and meaning of the "focus on hazard assessment as a screening tool" is not clear. The framework as written addresses both hazard and risk.

CHARGE QUESTION # 2

2. Are the issues raised in the Action Plan--chemical speciation, bioavailability, bioaccumulation, persistence, and toxicity--the major issues of concern for improving EPA's scientific assessments of the hazards and risks of metals?

Costa

Toxicity itself encompasses persistence, bioaccumulation and bioavailability and while these are important issues with regard to metal toxicity assessment the word toxicity involves these other issues. I would use the word adverse health effects instead of the word toxicity so that the issues are more equivalent and parallel.

While chemical speciation is extremely important in assessing a metal's health risk one needs to put the problem in perspective by giving more sophisticated examples. Certainly the methylation of inorganic Hg alters its toxicological parameters but the speed with which this process can occur in the environment has been overstated. For example in Minimata bay it is stated in many textbooks that inorganic Hg was dumped into the bay and it was changed to methyl Hg but this process would have taken much longer than the time frame in which methyl Hg toxicity was observed (ie 50 or more years) so methyl Hg must have been released by the chemical company in the bay. Another interesting example is the detoxification that occurs when Cr VI is converted to CrIII but then one has to consider that in drinking water at its normal pH CrIII would not be very soluble. So the issues are very complex and need to be understood by experts in the field. It is difficult to generalize about all metals since each metal is very different. It is interesting to note that plants and animals may ingest Cr VI and accumulate Cr in their body but it is in the form of CrIII since their bodies will reduce the Cr VI to Cr III. Thus humans can safely ingest plants and animals that have been exposed to Cr VI, since it will be in the form of CIII and the toxicity of Cr III is 500 to 1000 times less than that of Cr VI. I think the document would be served quite well if some more of these complex and mechanistically based speciation and bioavailabilty issues are brought up and the document would also be served well by more statements addressing what uncertainty exists and how sure one is in using the available data to arrive at a conclusion. It should be noted that the Cr VI drinking water standard is based upon a German mouse cancer bioassay study which showed a very slight increase in the incidence of stomach cancer at 500 ppm Cr VI. The study was not adequate to be used for such risk assessment, but today we use the number derived from this study as the drinking water standard. (ie 50 ppb)

I think the document correctly identifies the fact that Pb is usually bioavailable regardless of its form and the document also says that the reason that humans experience more bioavailablilty is because of the acid stomach which solubilizes metals yet the acid stomach detoxifies Cr VI to Cr III so again it is difficult to generalize about all metals they are not the same and perhaps for this reason should be considered individually. Most of the examples cited in the document use only Cu, Hg or Pb but not the other metals and they should be more balanced. The examples used in the toxicity section tends to be more balanced .

I think a lot can be gained from understanding the mechanism of toxicity of metals. Here is an example of how important this can be: We always thought the toxicity and carcinogenicity of Ni compounds were related to their ability to enter cells and Ni3S2 for example is phagocytized by cells and produces high levels of Ni inside the cell. This finding was actually discovered by my lab. However now we know that a metal does not have to enter the cell to produce toxicity it merely has to activate a signaling pathway by interacting with the cell surface receptor. In fact many toxic actions of metals are now known to be manifested by this mechanism including the induction of metallothionein, and most other protein induction etc. This model puts less emphasis on the intracellular bioavailability of a metal but it still needs to interact with a cell and thus be solubilized. So in this case a soluble metal ion is more active. I did not see any discussion of signaling pathways in metal toxicity in this entire document. I did see a discussion of the ability of certain toxic metal ions to interfere with essential metal ions and this is very important in understanding metal assessment. There is quite a bit of genetic diversity in the human response to toxic metals and also children are more susceptible (ie Pb and the blood brain barrier) These issues need to be raised.

Hayes
The scientific issues raised (chemical speciation, bioavailability, bioaccumulation, persistence, and toxicity) in the Metals Action Plan (MAP) correctly identify the problem and the major challenges that need to be addressed at the Site-Specific, National Regulatory, and National Hazard/Risk Ranking levels for improved metals assessment.

<u>Speciation</u>

In the case of speciation, the MAP correctly identifies the importance and need to include an assessment of metal speciation and the inherent complexity in determining metal ion speciation especially compared to organic hazardous compounds. Generally speaking, only one form of an organic compound (with respect to its PBT properties) must be considered at a time, whereas with metals, various forms can exist simultaneously with one species predominating, depending on the aquatic conditions (e.g., pH, pe, presence of complexing ligands etc). Changes from one metal species to another can be reversible within a short time frame of concern. As pointed out in the document, given that the “free” metal ion is generally considered to be the most toxic form in aquatic routes of exposure (excluding the consideration of organic forms) methods are available for accounting for the impact of changes in dissolved ion

concentration, pH, pe, the presence of complexing ligands, and precipitation on the most toxic forms concentration. The document also fairly points out the importance of sorption process and solid phase associations in impacting availability and mobility of metals as well as aging processes that tend to “bury” metals over time within sediment and soil particles with which they associate to make metals relatively immobile and unavailable. In such cases where metal ions are “safely” sequestered, risk and hazard may be reduced significantly. All of these issues are important and if assessed accurately would improve the determination of the impact of speciation on the “free” metal ion concentration and aquatic exposure.

However, less information is provided about the impact of metals speciation on other exposure routes other than aquatic exposure including such routes as dietary, dermal, or inhalation of particles and, as a result, questions of speciation associated with those pathways are not as well covered. For example, the importance of particle size (inhalation route) and surface area for solid phase associated metals are not mentioned per say but these might be expected to be quite important issues in that the rate of dissolution and extent of exposure of sorbed contaminants in the gut through ingestion or in the lungs through inhalation may largely determine the ultimate harm from a given form. Nonetheless, the document does not claim to be all inclusive, however, a better balance and mention of the impact of speciation in assessment of risk needs based on other exposure pathways needs would improve the Framework background on speciation.

The discussion of speciation in the context of Site-Specific, National Regulatory, and National Hazard/Risk Ranking and Characterization levels was given based on how speciation is currently being used a different regulatory levels. For example, it is stated that at the Site-Specific level, metal speciation information can be used to refine estimates of “toxicity, bioavailability, mobility, persistence, and source apportionment.” In contrast, at the National Regulatory level, the basis for regulatory assessments is often made based on the toxic form of metal (e.g., the solid metal alloys or mineral phases) with questions of speciation coming up in the context of fate and transport modeling and the concentration of the toxic aqueous form that can be expected to result in the receiving water (aquatic toxicity pathway) or in the case of assessing hazards directly associated with solid forms and metal release, the expected leaching potential of metals from the solid form can be assessed based on solid phase speciation issues (aquatic toxicity potential). At the National Hazard/Risk Ranking and Characterization level, the MAP points out that metal speciation is currently not routinely incorporated in the assessment approaches per say but rather the presence of PBT metals in materials are used to classify hazards. Examples are given in this context for air toxics as well as solid hazardous wastes have been classified in this way. No mention, however, is made about how liquid or aqueous products or waste containing metals are classified but again as long as the Framework points to the importance of risk and hazard across ranges in media, exposure, regulatory level, and metal class (as it is expected to), then having a limited number of examples of each is acceptable.

Bioavailability

Bioavailability is also a major scientific issue that is captured in the MAP. In the environmental remediation field, having usable bioavailability information has been considered one of the key missing components for determining the relative risk and hazard potential for a contaminated site. Yet, assessing bioavailability is still at a research-level with many questions unanswered about the best approaches to apply for a given situation. A Recently implemented and federally-sponsored research programs (EPA, ONR, HSF Joint Program in Bioremediation) was devoted to supporting work that on bioavailability. I am also aware of an upcoming NRC report devoted to pointing out the current state-of-the-art, tools, and limitations for assessing bioavailability in soils and sediments. A variety of approaches have been developed to assess bioavailability (chemical extractions, organism-specific bioassays, reported systems, biomarkers etc.), but not much has made its way into the regulatory arena except in some limited site-specific cases. If effective methods can be established, standardize and validated for use at various regulatory levels, utilizing bioavailability information can reduce the uncertainty associated with assessing risk and hazard, particularly the overestimation of risk based on total metal concentration levels alone.

Bioaccumulation

This has been considered one of the most important properties to measure as part of the "PBT" characterization of hazard chemicals. Yet, for metals, bioaccumulation data is less straight forward to evaluate and measure in a relative sense due to the essentiality of some metals to living systems and the various methods organism have adapted to regulate and detoxify (and therefore expunge metals) from their systems. While the connection with bioaccumulation and potential harm has been more easily confirmed with organic compounds and simple organic properties (e.g., Kow), no similar properties of metals have been found to correlate as well with accumulation and harm to ecological and human receptors. Nonetheless, the potential for accumulated metals to later become available or be transferred up the food chain remains a concern so the bioaccumulation extent remains an important one, if not a more complicated one, to assess for metals. The MAP properly categorizes this as an important issue but how to categorize relative risk and hazard of metals based on bioaccumulation properties is less obvious from the presentation (perhaps because at this point how to do so is unkown). In this regard, the MAP properly identifies the limitations of the current methods and the need to find ways to obtain and index bioaccumulation information for assessing comparative risk and hazard of metals.

Persistence

Is this a major scientific issue to include in the MAP? To the extent that persistence needs to be redefined in the context of metals makes, it essential to discuss in the MAP. But as a measure of risk or hazard, metals should not be considered infinitely persistent. An alternate definition is provided and cited in the background section on

persistence (DiToro et al., 2001) in which it is stated that “Persistence is a characteristic of a metal that is indicative of the constancy and duration of exposure of the available metal forms in a particularly medium.” Recognizing the limitation of ranking all metals as infinitely persistent is a good starting point of the discussion about how one should consider persistence (if at all) in the assessment. In addition, recognizing that persistence can be bad or good with metals must be understood in such an analysis. Knowing how long a metal stays in a particular form (half-life) and then making the assessments of the impact of that form on risk and hazard makes much more sense that giving a negative connotation to all metals. As correctly pointed out in this section, metals in some forms (i.e., as part of low solubility metal solids or highly sequestered by effective sorbents) may reduce risk and hazard. Examples that come to mind include the potential use of EDTA and carbon to treat accidental poisonings (metals and organics), the use of mineral apatites for sequestration of Pb which when ingested in this form are not easily dissolved to a significant extent even by gastric fluids (at low pH), or the effective sequestration of metals and radionuclides by zeolites or other solid phase associations for ecosystem protection. In these cases, having infinite persistence in the solid form is protective and desirable. So evaluating persistence for use in risk and hazard assessment of metals should be based on the relative persistence of different species and the relative harm that a given species may cause. In this context, persistence can be rated as a “good” or “bad” quality depending on the speciation and half-life information on persistence. But as a *de facto* negative property of metals, persistence should not be used in metal assessments.

Toxicity

Toxicity is clearly an important issue to consider in evaluating metals hazard and risk and probably the most important for to establishing relative indices risks for metals. The key questions remains as how best to perform appropriate toxicity tests that are generalizable to human and ecological receptors, and that can account for the different metal forms of hazards. In the context of toxicity, it is important to consider metal mixtures and potential synergistic and antagonistic effects of mixtures. Impacts of mixture properties was not considered in the MAP. Inasmuch as metal ion speciation and bioavailability of metals will impact toxicity, speciation and bioavailability need to be considered in the potential toxicity of different metal forms.

Scientific Issues not raised that need to be considered in MAP

Synergism/Antagonism

From previous panel phone discussions, the potential impact of complex metal mixtures on the assessment of risk and hazard has been identified as an important issue. This should be addressed somewhere in the MAP. Perhaps pertinent questions are: Does mixture complexity need to be considered at all regulatory levels? Do current data sets exist and methods (for evaluating speciation, bioavailability, bioaccumulation, persistence, and toxicity) to assess potential risk and hazard of metals in complex

mixture exposure formulations? How or should single metal tests be used in risk and hazard assessment at the various regulatory levels?

Data gaps and Uncertainties

Information is missing about important data gaps and the uncertainties in data for performing metals risk and hazard assessment at the different regulatory levels for the scientific issues of speciation, bioavailability, bioaccumulation, persistence and toxicity. The questioned of data quality and uncertainty was also raised (although tangentially) in the comments in the document "Agency's Quality System and the Draft Action Plan" provided by John Maney. A section in the MAP on data gaps and uncertainty or incorporation of this information into the speciation, bioavailability, bioaccumulation, persistence, and toxicity sections seems warranted. If this is not feasible because the data is not well known by the MAP panel or available in general, then the Framework should make as part of its plan, an assessment of the data gaps and uncertainties for the targeted scientific issues.

Other concerns

I had the impression that the major template for MAP was based on parallel assessment approaches that have been successfully established for assessing organic chemical risks and hazards at the various assessment levels. This has lead to the inclusion of bioaccumulation and persistence issues (i.e., PBT approach) as key elements that need to be considered to improve EPA ability to make better assessment of metals risk and hazard. But per the input the panel has received to date and my own understanding (although limited) of bioaccumulation and persistence, the approaches for assessment akin to those available for organics (e.g., Kow or half-lives for bioaccumulation and persistence) may not find their parallel to use as simple relative indicators of risk and hazard for metals. While for site-specific assessments, the lack of comparable indicators for metals compared to organics may not be a problem, as long as one collects the needed data on site, at the higher assessment levels, bioaccumulation numbers and persistence data may not find wide acceptance or useful generalizations for metals. If that is the case, then maybe these terms are not the correct ones for framing the assessment of hazard and risk for metals at these levels. For example, if BAF and BCF are not directly associated with hazard and risk for a given test species due to issue of essentiality versus non-essentiality and the species-specific metal are regulated and detoxified in a given species, then perhaps these should be dropped in favor of as yet to be developed approaches rather than continuing to place emphasis on fitting metals into this mold. Or if that is too radical, then perhaps the Framework needs to be more clear that alternatives will need to be found and that the current state of the science is inadequate for using bioaccumulation in risk and hazard assessment. From my reading arguments favoring not using the indicators such as BCF and BAF for metals assessment have been convincingly made. If, tissue concentrations (as measured by BCF) result more from the metal regulatory needs of an organism rather than from exposure concentrations, and toxicity results from exceeding concentrations

levels that an organisms has the ability to regulate and detoxify, then using these type of indexing approaches as part of the assessment of hazard and risk for metals seems fraught with pitfalls from the start.

Similarly, the notion of persistence is not appropriate as a negative indicator of risk and hazard for metals as it is for organic contaminants (see discussion above). So perhaps persistence should be cast in a different light from the outset as well.

Question: Should the MAP Framework assume from the start that the PBT approach is best for metals assessment at all regulatory levels or should part of the MAP Framework be to consider the differences between metals and organics, and in that light, consider alternative approaches from PBT approach for assessing relative risk and hazard?

Friedland

I agree with Max's observation that certain aspects of the situation at Minimata Bay have been overstated. And I have heard of the idea that chromium toxicity has also been overstated but don't know much about the subject firsthand. I am predisposed to believe that except for lead, many of the "problems" have been overstated. So I am sympathetic to the general views expressed in the paragraphs by Max.

In terrestrial ecosystems, very often the presence or absence of organic matter is more important than speciation. For lead and aluminum in soil water and sometimes in surface waters, if there is ample organic matter to complex with the metals, their bioavailability and hence their toxicity will be much less. Kim Hayes, Do you agree/have some additional examples in this area? In plants, it is hard to determine if the plants are effective at excluding large metal ions from root uptake or if the presence of organic matter makes the uptake more difficult. But the outcome is the same. For the most part, the presence of large quantities of organic matter, such as in forest soils, is more important than speciation in affecting woody plants. This should be reflected in the document.

Then there is the issue of synergistic effects: the parameters listed in the Action Plan are not evaluated in any human or natural system in the absence of other metals. Microorganisms in soils are affected by a variety of metals that are present both naturally and due to anthropogenic activity. The respiration that occurs in soils is influenced by the sum of these metals. I just don't know if single metal-organism evaluations of toxicity are sufficient. Is there an analogous situation in human or mammalian systems? Can we discuss synergistic effects in a broad sense and suggest that interactions between metals must be considered in all systems? And if the answer is yes, how can we establish broadly applicable standards?

The last part of Max's response refers to genetic diversity in human response. I imagine there is also variation in human response and I know there is variation in plant

and animal response resulting from differences in nutrition, health and stress levels. Should these be incorporated into the document? With forests, individual trees that have been generally weakened (or predisposed) by one pollutant, such as acidic deposition, could then be more vulnerable to a second pollutant, such as a toxic metal.

Windom

Issue: Technical Capacity Building

Any Action Plan for the assessment of metals in the environment should address the issue of the technical capability for implementation. Just because we recognize that concentrations of metals are of environmental concern at levels lower than previously believed and/or specific forms are the culprit, doesn't assure that technical competence to make appropriate assessments is widespread. Mercury is a good example. While reporting levels for Hg in discharges from municipal treatment facilities have been reduced significantly, the required analytical capability is relatively limited. Understanding the distribution/rate of formation of methylmercury in the environment is critical to understanding its fate and potential environmental impact, but few labs can quantify this compound in environmental media at ambient levels. In fact, it can be generally stated that when it comes to addressing metal speciation in the environment, technical capability is very limited globally.

Any plan that proposes new approaches should include an assessment of technical capabilities and a plan for capacity building within and outside the agency. EPA does this; (an example is the relatively recently new standard Methods for HG and metal analyses), but there is not much "marketing" or training. The AP should at least include what role the Agency should play in the overall enterprise of method development, training and outreach.

Thomas

The issues raised in the Action Plan emphasize the scientific issues important for assessments focusing on a single metal in a specific location and risk scenario. But the Action Plan does not directly or clearly address the scientific issues important for integrated, multi-stressor assessments that include metals. Integrated assessments include, for example, comparative risk studies, national priority-setting studies, and some broad international environmental efforts.

The Draft Action Plan was developed based on concerns about the TRI Lead Rule and international PBT activities, both of which involve the integrated type of assessment referred to above. To some extent the Draft Action Plan does address the specific issues raised by the Lead Rule and PBT assessments. But in developing this overall framework, the Agency is seeking not just specific approaches for these two cases, but a more general approach.

In this context, I suggest that the Agency devote greater attention to the scientific challenges of integration. The methods and measures that have been used for integrated assessments do not yet link well to the reductionist risk assessment approaches used for single stressors at well-characterized sites. Perhaps because of the inability to use detailed risk assessment for integrated studies, there has developed an increasingly philosophical divide. Integrated assessments currently match well with precautionary-principle, hazard-based policy, while the reductionist, single-pollutant risk assessment approach more accurately characterizes risk but is difficult to apply at a strategic level.

In this Draft Action Plan, the Agency appears to be seeking ways to bridge the methodological gap between integrated assessments and risk assessment. This is an important task for the future of environmental policy, and the Agency should be lauded for this initiative. However, this is not an area for which there is as yet a well-developed scientific framework. It appears that the Agency's current approach is to try to extend the highly detailed, reductionist approaches to the integrated cases. While this will work to some extent and in some cases, development of a more general approach will also require understanding of how to scale up analyses. That is, there is need for fundamental understanding of when, how, and why the comparative assessment of 100 environmental stressors is different from the sum of 100 assessments.

For general, multi-stressor evaluations, the key scientific issues include both how to incorporate more detail into the assessments, as well as what are the best ways of simplifying the analysis. Simplification, integration, and scaling are the issues that need to be understood for integrated assessments. The mention of sensitivity analysis is an important step in the right direction.
The background section suggests that risk assessments for metals are more complex and difficult than for organic compounds. This is not always true. Consider, for example, two recent major national assessments, the Mercury Report to Congress (EPA 1996) and the Dioxin Reassessment (EPA 2000). The uncertainties in the mercury assessment are very large; but they are no greater than the uncertainties in the dioxin reassessment. The EPA developed a model of the transport, fate, speciation, and bioavailability of mercury, but did not attempt so ambitious an assessment for dioxin.

Likewise, in comparative risk studies, the risks of metals are not more uncertain or more difficult to characterize than the risks from organic pollutants or other environmental stressors. Much more is known about lead, and even mercury, in comparison with less well studied stressors such as edocrine disruptors (NJ DEP, 2002). In human health risk ranking exercises, the risks from metals typically have lower uncertainty ratings than the risks from non-metal environmental stressors. In ecological risk ranking exercises, the uncertainty in the metals assessments are typically greater than the assessment of stressors such as habitat loss, but the metals risk assessments have comparable uncertainty to the assessments of risks from organic compounds such as PCBs (NJ DEP; Harwell et al. 2001).

This is not to say that comparative risk studies characterize metals risks correctly or well. But because metals have been studied in more detail than many other important environmental stressors, the development of a framework for metals might be considered as a "warm-up" exercise to the development of more general frameworks.

The Action Plan makes broad generalizations, but provides only a limited number of examples. It would be enormously helpful if the Agency could show several example calculations (e.g. "before" and "after" calculations) that would demonstrate how the framework would be applied.

References

NJ DEP (New Jersey Department of Environmental Protection), 2002. New Jersey Comparative Risk Project.

Harwell, M. 200? Ecosystem Risks Ranking.

US EPA, 1996. Mercury Study: Report to Congress. EPA-452/R-96-001c

US EPA, 2000. Dioxin Reassessment.

CHARGE QUESTION # 3

3. Has EPA adequately characterized the issues and do the summaries adequately capture the key scientific uncertainties that will need to be addressed by the Framework and the Guidance?

Hayes

Although the background in large measure captures the essential questions of metal properties (speciation, bioavailability, bioaccumulation, persistence, and toxicity) needed for assessment at a variety of regulatory levels, in some cases the Summary Issues raised did not always seem to follow directly from the background information provided.

Speciation:

Issues Presented:

Issue Summary No. 2.1.1: Incorporating Speciation at Different Assessment Levels (Site-Specific, National Regulatory, and National Ranking); What are the data needs and do we have the necessary approaches for incorporating metal speciation into assessments at the different levels?

Not much information was provided about the types of speciation data needed at each assessment level to support the issue as raised at the end of the section. Yet data

needs were cited as a big issue. For example, at the Site-Specific regulatory level, we may need very complex speciation data for which on-going research is providing many answers, but much is still at a research level (e.g, characterizing the solid phase associations of metals at surfaces and in mineral phases). Estimating the relative mobility of metals in complex natural environments requires obtaining speciation data that is not always available but must be measured at the site (can be expensive). At the National Regulatory level, the speciation data may not be as extensive. For example, all that is needed is to categorize whether the metal form of concern is solid or aqueous. At this National level, leaching tests for solids or thermodynamic data bases for speciation calculations may be needed for fate and transport modeling in order to assess the potential harm under various scenarios. At the National Hazard/Risk and Characterization level, detailed speciation data as a function of changing conditions may be even less important where form of a metal in a particular waste type (solid, liquid, or gaseous) might be what is needed. At this National level, the type of data needs may be more of metal form (solid or aqueous) and concentration composition for assessing relative concerns about metal products and waste streams. Perhaps more information about speciation data needs for the different assessment levels should be given, if this is the issue is naturally follow from the background.

Issue Summary No. 2.1.2: Grouping of Compounds of the Same Metal. Do approaches exist that allow group of metals into classes for the purposes of assessment?

While it is important to know if we can group metals for classification and assessment purposes, the background did not give much motivation for this line of thinking either, except in the discussion of metal aquatic toxicity using chemical speciation and the Biotic Ligand Model (DiToro et al., 2001). In this case, it was clear that the relative ranking of metals for setting standards may be accomplished for aqueous metals as a group. I believe other examples such as considering organic metal forms as a separate class (where PBT approaches that are used for organics can be used, e.g., Kow, BCF etc.) or group solid forms together and performing leaching tests could have been stated. The background discussed some of these issues but a more organized approach around the issue would be better than listing the issues at the end.

Issue Summary No. 2.1.3: Efficacy of Creating Generalized Assessment Scenarios. What uncertainties would this raise and under what circumstances are such scenarios warranted to establish hazard priorities?

This issue was also raised at the end of the speciation section but was directly targeted to the speciation issue *per say* but more generally as to whether all of the various pieces of information (speciation, bioavailability, bioaccumulation, persistence, and toxicity) could or should be used for general prediction of hazard for various scenarios. One of the benefits of utilizing speciation information, is that if enough data are available and of sufficient quality, speciation models can be very good at predicting the impact of change on metal form, mobility and toxicity. This type of exercise, however, is very dependent on the quality of data and existence of enough data. In many cases

speciation models can do a good job of relative assessment in a comparative analysis. As such, if the background had provided a better motivation for the utility of speciation models and the importance of the quality of the data (and what data exists!), it would have made it clearer how this issue fits in with speciation and why utilizing of speciation can be so important.

Bioavailability

The background makes it clear that bioavailability has not been utilized except in site-specific ways and that the basis for this is lack of bioavailability data, and the species specific nature of this assessment. However, not all of the issues raised are supported by the background information provided.

Issues presented:

Issue Summary No. 2.2.1: Bioavailability information to date has been used in site-specific assessment. How can bioavailability information be incorporated into the National Regulatory and Hazard ranking and priority assessment levels for differentiating among metals?

Issue Summary No. 2.2.2: Bioavailability approaches exist for metals in aquatic environments, but the state of the science is less developed for humans and wildlife in terrestrial settings. How can bioavailability information be used for these receptors and for hazard ranking and priorities.

Issue Summary No. 2.2.3: It is stated that lack of data and models for assessing/ predicting gut absorption of ingested metals, dissolution of ingested metals, and biota-specific detoxification of metals is a major cause of the lack of addressing bioavailability in assessment. What methods should be applied or developed to address theses complexities.

Issue Summary No. 2.2.4: Toxicity tests to assess hazard or risk are largely based on test animals exposed to soluble metal salts. What methods or approaches should be applied to reduce the uncertainty resulting for current methods used in mammalian toxicity tests?

Issue Summary No. 2.2.5: When doing national level assessments, how should the Agency address background level metals and have criteria that are conservative and protective of human health?

The background provides some motivation for Issues 2.2.1 and 2.2.4, but little or no information is given to support Summary Issues 2.2.2, 2.2.3, and 2.2.5.

In the case of Issue 2.2.2., it would be useful to give some examples of the types of bioavailability approaches that are more fully developed for aquatic environments

compared to humans and wildlife. A reference, for example, of the many types of bioassay uptake or toxicity tests (and their limitations) that have been developed for plants, invertebrates, and fish in aquatic settings would have been supportive of this statement. On the other side, the mention of the dearth of studies on humans or wildlife surrogates would have been helpful. One could also mention the type of information or tests that have been used for assessing bioavailability in humans. A case in point in the recent use of *in vivo* young swine tests to simulate Pb uptake for children (and the corresponding *in vitro* Pb uptake studies that have been shown to correlate well with the young swine tests (Drexler et al., 2000). But the fact that this is one of the only studies of its kind so far with metals to relate *in vitro* to *in vivo* studies, is good evidence to use in support of the statement.

In Issue 2.2.3, lack of uptake data from ingestion studies, dissolution of ingested metals, and species-specific nature of detoxification are listed as a major complicating issues to using bioavailability data but not much supporting information is provided on what data has been collected or not. Perhaps this could be qualified to indicate that much is known in a few cases but not for many metals if this is the point that is being made. Maybe a better question would be can bioavailability approaches that have been tested for certain metals, media, and species be more generally applied for other metals and media. Again a few examples of what is known versus what is not would be helpful in setting up the major issue questions. Also note that much could be added to describe the variety of tools that are used to assess various aspects of bioavailability from a metal release potential (such as chemical extractions, in vitro gut tests etc.). These tools and what they can be used for may be beyond the scope of this discussion but they may be appropriate to mention in the sense of what approaches might be used to attempt to establish relative bioavailability concerns in various contexts.

No discussion about the issue of background concentrations is raised in the bioavailability section background, yet this is added as an important Summary Issue 2.2.5 at the end of the bioavailability section. I am aware, for example, of studies that have identified the source of groundwater contamination by As due to the natural weathering As containing minerals rather than due to anthropogenic inputs. Establishing and distinguishing background from other sources is important but was not discussed in this section.

Bioaccumulation

Issues Presented:

Issue Summary No. 2.3.1: Metals Essentiality, Regulation, and Interpretation of Bioaccumulation Data. What Approaches are appropriate for considering essentiality, of metals in assessing bioaccumulation potential? When BAF/BCF values depend on exposure concentration, can such data be used reliably for assessment? If so, what approaches are best?

Issue Summary No. 2.3.2: Factors Affecting Bioaccumulation. Given the present state of the science, to what extent can the Agency use current or emerging approaches to incorporate factors affecting bioaccumulation by aquatic organisms for improving estimates and predictions of metals bioaccumulation?

Issue Summary No. 2.3.3: Assessing Hazard from Bioaccumulation in Terrestrial Organisms. Given the importance of metal bioaccumulation in the terrestrial ecosystems, how can the Agency apply existing and emerging tools to quantify bioaccumulation for estimating and ranking bioaccumulation hazard potential of metals? Are there reliable ways in which mammalian pharmacokinetic data can be represented in the form of indices that are analogous to BCF and BAF for aquatic species?

Issue Summary No. 2.3.4: Selecting/Weighting Bioaccumulation Data for Different Species. When classifying the hazards of metals according to their bioaccumulation potential, should the bioaccumulation data for some species be excluded (or disproportionately weighted? If so, which species? Should metal hazard evaluations be made in the context of predefined exposure scenarios (e.g., human health, terrestrial, and aquatic dependent wildlife) in an effort to reduce uncertainty associated with combining independent indicators of hazard potential (e.g.,toxicity, persistence, bioaccumulation etc.)?

Issue Summary No. 2.3.5: Interdependence of Bioaccumulation and Toxicity in Characterizing Metal Hazard. In situations in which the metal under review causes toxicity to a certain organism, and the metal also bioaccumulates in the same organism, should bioaccumulation be considered independently of toxicity, and if so, what are the important factors that need to be considered regarding the use of these data for hazard identification or hazard ranking purposes?

Each of the above issues was well supported by the arguments presented in the section devoted to explaining the issue. It would have been useful (appropriate) if a similar level of discussion was provided in the other scientific issue sections (e.g., speciation, bioavailability, persistence, and toxicity). As mentioned above under speciation and bioavailability, the Summary Issues were stated but not always well motivated by the general background discussion provided. The same lack of discussion exists in the persistence and toxicity section (see below). With respect to the Bioaccumulation Summary Issues (2.3.1.- 2.3.5), they pose important questions that need answering. With respect to Summary Issue 2.3.1, supplementary information provided to the panel suggests that BAF/BCF approached from aquatic organism studies should not be used. However, it is appropriate in the development of the Framework that this question be raised. This point is reinforced in Summary Issue 2.3.3 which ask the question as to whether mammalian pharmacologically data can be used as a substitute for BAF/BCF approach. Summary Issue 2.3.2 correctly indicates that many factors affect bioaccumulation and that methods are needed to account for these effects if bioaccumulation data is to be used to rank hazards and risk for metals. Summary Issue 2.3.4 points out the problem associated with species-dependent aspects of

bioaccumulation data and how these should be factored into the risk and hazard assessment analysis. Determining what organisms represent the most important receptors for assessing both aquatic and terrestrial risk and hazard is certainly one of the key questions. Summary Issues 2.3.5 addresses the question of whether bioaccumulation and toxicity data should be considered independently in an assessment when in many cases toxicity is related to bioaccumulation. This points to the need to evaluate the merits of the PBT approach, in general, and how one should weight the information in the ranking of risk and hazard. Perhaps the "B" in the PBT concept for metals needs to be reconsidered and perhaps this should be more explicitly stated in the Summary Issues and as an additional question to consider in the MAP.

Persistence

Issue Presented:

Issue Summary No. 2.4.1. While metals are infinitely persistent as elements, the "persistence" of specific metal compounds can vary with environmental conditions. What approaches can be used to determine when and how persistence should or should not be considered when conducting prioritization analysis? Is there an alternative way to define persistence of metals and/or metal compounds that could be used in national prioritization analyses that are designed to distinguish between metals?

The whole notion of considering "persistence" as one aspect of assessment for risk and hazards for metals is properly questioned in this section. An alternate definition is provided and cited in the background section (DiToro et al., 2001) in which it is stated that "Persistence is a characteristic of a metal that is indicative of the constancy and duration of exposure of the available metal forms in a particularly medium." Recognizing the limitation of ranking all metals as infinitely persistent is a good starting point of the discussion about how one should consider persistence (if at all) in the assessment. In addition, recognizing that persistence can be bad or good with metals must be understood in such an analysis. Knowing how long a metal stays in a particular form (half-life) and then making the assessments of the impact of that form on risk and hazard makes much more sense that giving a negative connotation to all metals. As correctly pointed out in this section, metals in some forms (i.e., low solubility metals or highly sequestered by effective sorbents) may be of benefit and reduce risk and hazard. Examples that come to mind include the potential use of EDTA and carbon to treat accidental poisonings (metals and organics), the use of mineral apatites for sequestration of Pb which when ingested in this form are not dissolved to a significant extent by gastric fluids, or the effective sequestration of metals and radionuclides by zeolites or other solid phase associations for ecosystem protection. In these cases, having infinite persistence in the solid form is protective and desirable. So the questioning of the use of persistence in PBT analysis for metals is clearly warranted.

Toxicity:

Issues Presented:

Issue Summary No. 2.5.1: Dose-response information (usually obtained from metal salt solutions) may not be directly related to risk and hazard due of metals and since metals can be in forms different from that used for dose-response tests and they may transform between different forms in response to changing environmental conditions? What are the data gaps limiting robust hazard and risk assessment from dose-response information? What methods could be used to account for the limitations in the existence of compound specific toxicity values when assessing metals-related hazard/risk?

Issue Summary No. 2.5.2. Metal ion speciation methods are needed to identify, collect, and quantify metals species in the environment. What are the limitations of the currently analytical methods to measure metal ion speciation? Which toxicity and exposure issues create demands for new analytical methods?

Summary Issue No. 2.5.3: Essentiality requires that dose-response relationships account for this in assigning reference doses (RfDs) and reference concentrations (RfCs). Should existing risk assessment methods be modified to account for essentiality? If so, what options should be considered?

The questions raised here are important ones. Background supports the need for including essentiality for establishing RfDs and RfCs (Issue 2.5.3) to assess the potential for risk. A speciation section points out the importance of relating toxicity to speciation (with toxicity depending on valence, soluble versus insoluble forms, and exposure pathway; Issue 2.5.3) but that the correct speciation is not often known. Further, the need to recognize the limitation of speciation data and analytical measurements (Issue 2.5.2) including data uncertainty is important but this issue might have been more appropriately introduced and handled in the Speciation Section (2.1) rather here under Toxicity (2.5). Not much information was given in this section about the limitations in using dose-response studies for assessing relative toxicity but this Summary issue is appropriately raised (Issue 2.5.1). The question is how effectively dose-response relationships based on exposure to metal salts and for particularly can extrapolated to complex scenarios where predominant metal ion speciation and receptor is different. Examples of the organism-specific nature of the dose-response relationship and cited examples of the dependency of toxicity on metal form would have helpful. Some aspects of the limitations of the dose-response toxicity tests are made in the other sections of the MAP (e.g., in the context of bioaccumulation and bioavailability) but more specific reference to specific toxicity studies would have be useful to support the issue raised.

<u>Issues not raised or not adequately raised that are potentially important:</u>

<u>Synergism:</u>

From previous panel discussions, synergism or the potential impact of complex metal mixtures on the assessment of risk and hazard has been identified as an important issue. This should be addressed somewhere in the MAP. Does mixture complexity need to be considered at all regulatory levels? Do current data sets exist (speciation, bioavailability, bioaccumulation, persistence, and toxicity) to assess potential risk and hazard of metals in complex mixture exposure formulations? How or should single metal tests be used in risk and hazard assessment at the various regulatory levels?

Uncertainties:

Information is missing about important data gaps and the uncertainties in data for performing metals risk and hazard assessment at the different regulatory levels. This questioned was also raised (although tangentially) in the comments on the Agency's Quality System and the Draft Action Plan document provided by John Maney. A section on data gaps and uncertainty in speciation, bioavailability, bioaccumulation, persistence, and toxicity data seems warranted. If not well known, then the Framework should make as part of its plan an assessment of the data gaps and uncertainties.

Summary of Comments:

1. Except for the Bioaccumulation Section (2.3), many Summary Issues raised in the other sections (2.1, 2.2, 2.4, and 2.5) lacked sufficient supporting statements and citations of literature. More supporting information should be provided in these cases, and perhaps each section be modeled after the bioaccumulation section to make sure the MAP supports and leads more naturally to the issues raised.

2. An identification of the data gaps in speciation, bioavailability, bioaccumulation, persistence and toxicity and the relative uncertainty of data and relative uncertainty of data is needed in the context of the various regulatory levels in the Framework Plan. This could be stated as an important task of the Framework for metals assessment or provided perhaps, in part, as a section in the MAP.

3. Synergism, antagonism, and metal mixture effects should be discussed in the MAP or considered as an important element in the MAP Framework and Guidance Plan.

Windom

The Action Plan over emphasizes the expectations related to attention to chemical speciation

In the Action Plan (AP), the chemical speciation issues appear to be elevated to a level above the state-of the-science. To the uninitiated reader, it provides expectation which will be difficult to achieve and may not meet the test of "sound science". The penultimate paragraph on p. 10 gives some perspective in that it points out that we have at least, advanced to the point where AWQC for metals is based on "dissolved"

concentrations rather than total recoverable metal levels. But it goes on to imply that the Agency may be in a position to regulate metals in the environment based on the toxicity of specific forms of metals.

While it may be useful to identify which metal species are most toxic through laboratory bioassays, it is a giant step to apply these results to the real world based on thermochemical models. Models are useful tools to direct research, but they are only as good as the input data. The real world includes numerous unknown organic ligands, particles, ion strength, etc. which may vary on small spatial and temporal scales.

On a national scale, speciation-toxicity models may be useful in assessing metal hazard profiles. But these models should be coupled to real data on metal partitioning between solid and aqueous phases to get a sense of the likely importance of the toxic species in real system and which might be at greater risk. On a site specific basis, models such as that described by DiToro et al. (2001), would be of limited use, perhaps only applicable to prioritizing among various highly contaminated sites similar to the usefulness of the AVS-SEM model.

There is, of course, a technical issue related to any aspect of the AP involving chemical speciation. For the Framework and the associated Guidance to be useful, methodologies should be amenable to standardization, calibration and validation (i.e. quality assured). Many models depend on data which are often obtained by operationally defined methods with limited mechanisms (e.g. standard reference materials, etc.) for QA/QC so that accuracy, bias and uncertainty can be assessed.

Uncertainty related to chemical speciation

The uncertainties associated with the extrapolation of laboratory studies and models to assess toxicity of specific metal forms to real environments is not discussed in enough detail in the AP. The purpose of laboratory experiments is to evaluate processes under specified constraints. Attempts to mimic nature in microcosms are always accompanied by large uncertainties. CEPEX, MERL and other mesocosm programs strived to eliminate some of these uncertainties but results demonstrate that this is not totally possible, even in large experimental systems.

Thermochemical models (or all models for that matter) also attempt to mimic nature. But they are only as good as the data that goes into them. For example, water quality models used to estimate metal speciation have dissociation, solubility, etc. constants/coefficient associated with chemical reaction all of which have uncertainties, but of more concern are the reactions (for example with unknown/unaccounted for ligand and or particles) which are not included in the model.

When both of these sources of scientific uncertainty are incorporated into the AP concern is raised as to how useful the approach might be. For establishing hazard rankings, toxicity of chemical species assessed by bioassay/thermochemical models

may be quite useful even given the associated uncertainties. If the application of these data is to be extrapolated further, uncertainties increase. The AP needs to address this.

Uncertainties related to issue of persistence

As the AP points out clearly, the concept of persistence must be assess for metals differently from organic contaminants (although for certain metal compounds such as tributyltin the model for organic contaminant persistence probably applies). Different approaches to the issue of persistence are mentioned in the AP, each with associated uncertainty.

Persistence of the toxic form(s) of the metal seems to be the implied approach in the AP. But how do you obtain empirical data for variable environmental conditions, particularly when the analytical requirements are substantial, not to mention the QA which must accompany this approach.

Partitioning of metals between phases (vapor, aqueous, solid) and or compartments (air, particle, soil, sediment, water and biota?) and the kinetics of the processes would have less uncertainty. This approach has the further advantages that considerable data already exist and the QA associated with acquiring such is reasonably straight forward. Determining environmental controls on partitioning is likely to have much less uncertainty associated with it than determining environmental controls on chemical speciation.

CHARGE QUESTION # 4

4. Can the SAB suggest priorities within the list of issues based on (a) the potential impact on the assessment of risk or hazard and (b) the state-of-the-science and the feasibility of developing guidance in the near term?

Tran

a) It may be useful to consider priority issues in context of the regulatory purpose and whether it is concerning human or ecological risks. Suggested priorities that are based on human health and in context of risk ranking might be as followed: 1st speciation; 2nd bioavailability; 3rd toxicity; 4th bioaccumulation and 5th persistence. For a risk ranking purpose, perhaps, the most crucial information is speciation, as it is one key determinant of mobility, bioavailability and bioaccumulation; and toxicity. Approaches for extrapolation across different environmental settings, different metals, or among different form of same metals, grouping of different compounds of same metal and broad generalizations about environmental fate and effects with standardized scenarios,

and explicit accounting of uncertainties associated with such science-policy approach should be developed.

b) So much information/knowledge presented in the MAP is based on aquatic toxicity – it is perhaps feasible to develop guidance that would focus in this area in the near term. The agency could utilize the approaches for aquatics as pilot and lessons learned from this pilot can be utilized to develop other guidance.

Hayes

This is a tough question. Certainly incorporating metal ion speciation and bioavailability tools for metals is essential element (as pointed out in the MAP) to accurately assess risk and hazard at the site-specific level and will be essential to properly determine, e.g., which sites and exposure pathways introduce the greatest hazard and risk to an exposed population, and where immediate action is needed to protect the public. Making progress to incorporating these two elements should be high on the list. At the higher regulatory levels, as pointed out by Stakeholders in Section 1 on page 5, critical issues are finding alternative methods for bioaccumulation (in view of inadequacy of BCF and BAF indices for metals), determining what is significant bioaccumulation of metals in humans, and incorporating speciation, transformation, and bioavailability information in models and risk criteria evaluation is important. Likewise, finding good approaches for measuring relative toxicity harm of metals for humans should be high on the list. The state of the science is such that for complicated systems, speciation questions and bioavailability issues may be difficult to address on absolute terms, but assessing relative impacts of solutions conditions, or distinguishing elements from substances, or categorizing metals in terms of form (organic vs inorganic, solid vs., liquid) is obtainable information that could yield results in the short term. For example, tests can be performed using existing approaches and tools to assess relative risk of metals using real substances (uptake, leaching, persistence) and can improve our knowledge about the impact of metal form (crude speciation) on risk and hazard. The development of human based measures for all of the scientific issues raised is also important, but the payoff can not be expected right away. The design of appropriate indices at the higher assessment levels and the uncertainties associated with simplifying assumptions can only be substantially improved with better mechanistic understanding of the processes.

CHARGE QUESTION # 5

5. Are there specific recommendations for the Framework or for the ``Guidance for Characterization and Ranking of Metals'' (including methods and models) for addressing these issues that are not captured by EPA's Action Plan?

Tran

General comments:

Who are the intended audience for the MAP? The intended audience for the MAP should be stated.

What exactly is the Metal Action plan (MAP)? From the executive summary, it can be inferred that the MAP was written to facilitate and direct the authoring of two guidance documents (A Framework for Metals Assessment and Guidance for Characterizing and Ranking Metals) and outline the process of producing these documents in the form of Figure 1, on page 41. It should be noted that this SAB review is not part of that figure 1, thus it is unclear if this SAB review is part of the Action Plan. Although it might be a matter of terminology, when the term Action plan is used, a reader anticipates that an actual action plan with key action items and timeline explicitly presented in the introduction of the document.

In the executive summary, the following 4 worthy goals are stated:

1. A consistent application of scientific principles for assessing hazard and risk for metals –
2. State-of-the-science application of methods and data –
3. A transparent process (i.e. articulating assumptions and uncertainties),
4. The flexibility to address program-specific issues.

While it can be inferred from the MAP document that the agency will attempt to address the 4 objectives through the two cross-agency guidance documents, the ability to assess whether the Agency will meet these objectives is hindered by the fact that these documents are yet to be developed and the outlines for these documents lack the necessary details to allow such evaluation. While the MAP discusses a three-tiered approach, which sheds some light on the breadth of both technical and regulatory issues, the specifics on flexibility to accommodate program-specific needs is not provided. Also, how transparency and required documentation to achieve reproducibility in risk assessment (i.e. transparent process) is not discussed. More explicit indication as to the depth of technical details (via examples) that the Agency anticipates for these documents would be useful.

The state of science and data/models appeared to be less developed for human than ecological systems (particularly, aquatics). Furthermore, risks to humans and to ecological components vary widely for a given metal. The discussion on ecological versus human health risks need to be more clearly organized/delineated in terms of state of science, data/model availability for hazard and risk assessment. For clarity, it may be useful to develop Framework and Guidance documents to address ecological and human health issues separately.

Framework – In the following sections, comments specific to the Framework as outlined in the MAP are provided. Many of these comments reflect the need for more specificity in the level of details of the framework:

While the need for flexibility is among the stated goal of the MAP, this is not outlined in the purpose of the Framework document (section 1.1.1). It is recommended that flexibility to address 1) programmatic issues, 2) regulatory decisions, and 3) data availability is included.

As identified in the scope of the framework (section 1.1.2), the framework will supplement existing guidance and discuss key issues with metal-specific-information. In the MAP, the TRI-PBT framework is referred to (page 25 and 38). What are the current PBT frameworks under different EPA program offices? How might these be harmonized with the Metals guidance? It is also unclear if the framework would identify other existing regulatory guidance for which considerations of scientific matters outlined in the framework would be appropriate. A level of detail here would allow a better understanding of the intent.

It is further indicated that the framework (Regulatory application and implementation of the framework, section 5.0) will discuss and compare practices among the statutes for assessing hazards and risks of metals and metal compounds; and identify examples of the different tiers from statutes, regulatory guidance and criteria for risk management. A more detail and succinct discussion on these issues would provide reader/reviewer of the MAP a better perspective as to how state-of-the art and evolving scientific issues relating metal hazards and risks can be more consistently implemented given this mosaic of statutes, regs and guidance's.

The framework indicated a tiered approach (section 1.1.3). It is recommended that criteria/approach for transitioning from tier to tier and data quality objectives for each tier are described.

The framework references section 2 of the MAP for an overview of key issues (section 1.2). While comprehensive, additional discussion on the following issues would be useful:

-- Persistence –Metals can transform dynamically (both spatially and temporally) in response to controlling environmental conditions. It is

possible that overtime, a non-toxic form could transform to a more bioavailable and toxic form and vice versa. A discussion with regard to relevant time frame for risk assessment, i.e. truncation of time and scenarios that are temporally based (10, 20, 30, 50, 100 years, etc….into future) would be helpful in understanding the agency's perspectives.

-- Bioavailability – page 13 of the MAP indicated that while the availability of a metal in the environment is an important factor in determining its bioavailability in aquatic species, it appears to be considerably less important in controlling its bioavailability in humans or other terrestrial species….metal compounds that have limited availability in aquatic environments may have appreciable bioavailability in humans…pH in human guts as reason (oral). State of science is less developed for humans and wildlife. This speaks to the need for developing separate guidance for ecological versus human risks. The lack of data for humans would suggest that there is a need for lower tier assessment and science-policy assumptions. The separation of these systems would enhance transparency and clarity with regards the state of knowledge.

- Relative bioavailability concept needs to be described.

- Extant and ongoing exposure surveillance program for metals such as the NHANES/NCEH surveillance program -- how can these data be used and in national assessment and ranking?

- Synergistic effects, modifying effects of nutrition/diet, etc…, vulnerable population – highly exposed and biologically more sensitive receptors – these discussions should be included. Unique aspects of the toxicity of metal compounds to humans vs ecological systems also points to the need to separate guidance for human and ecological risks.

- Background was mentioned in the bioavailability section in context of site-specific assessment however with little discussion on the issues.

- Co-occurrence of metals with organics in the environment and effects on fate/transport (mobility)

Problem formulation and scope of analysis (section 2.0) indicate the likely scale of the assessment, both temporal and spatial. As such the conceptual models (section 2.5) should include temporal view. This is not currently explicit in this section.

The framework indicates principles to determine sensitive subpopulations that receive significant exposure of concern (Assessment of endpoint selection, section 2.4). How does this new framework apply to existing EPA's guidance on this issue, i.e. FQPA 99.9th percentile exposure? How would this promote consistent application of science

as indicated in the goal? Issues concerning biologically sensitive sub-population are not addressed but should be included in the framework.

Characterization of Exposure (section 3.1) – There are a number of extant environmental monitoring and human exposure surveillance such as those administered by NCEH/NHANES. Approaches to utilize these data for the metal hazard and risk assessment for regulatory purposes should be evaluated.

For both exposure characterization (section 3.1) and human health effects (section 3.2) -- Data quality objective for the various tier of assessment (appropriate for the regulatory scope) should be included in the framework. A process for periodic review and revision of science-policy SOPs where data are not available should be described. The framework should also address the need for documenting major sources of uncertainties.

Guidance for the Characterization and Ranking of Metals

The *goal of the Guidance* Document as extracted from the MAP (pages 34 and 35) are to

- document cross-agency guidance for applying the principles described in the Framework Document
- provide the tools and specific guidance for characterizing and assessing the hazards and risks of metals
- address critical needs identified by the stakeholders
- be applicable to situations of priority setting, categorization, and similar activities.

Besides the stated goals, little else was provided with regards to this Guidance document in the MAP. Outputs on preliminary hazard based ranking approach as one envisioned from the risk ranking guidance can be subject to a number of risk interpretation and use without proper presentation of ranking outputs. How the information is conveyed and criteria for sorting out top priorities should be articulated in the guidance documents.

Outreach/Other issues

Coordination with other federal agencies that would have relevant scientific data and information: NIOSH – worker exposure/outcome data; HHS (NCEH and NCHS) on human exposure surveillance/biomarker data; USDA/FDA data/approaches on assessing essential element.

States as stakeholders – any coordination/exchange of dialogues with states?

Other question -- Is there a need for other guidance -- for site-specific assessment? for National regulatory Assessment?

Fowler

Aside from general comments noted above in response to #1, the omission of a discussion of metal mixtures and the possible types of interactions (additive, synergistic, antagonistic) among metals /metalloids should be addressed in the document. There is a clear need to include such a discussion in relation to Superfund sites which frequently contain elemental mixtures. A growing number of investigators and other Federal agencies such as ATSDR are taking an active interest in this area. This means that in the near future, the database on metal-metal interactions will become more robust and it will be easier to incorporate new data into a regulatory framework that has already considered this issue. A discussion of metal mixtures from this perspective will indicate a current awareness and facilitate inclusion of interaction data as they are published.

Hayes

The Action Plan does not address the issue of synergism and antagonism that mixed metal systems may experience. The Framework needs to incorporate this concept as part of the Action Plan or make it a key question to address in the Framework. It was also not clear in the MAP Draft what data needs exist for modeling or setting criteria nor the relative uncertainties of data or how uncertainty will be addressed in the Action Plan. This aspect of the MAP needs to be made more transparent also in the Plan.

Many models and methods that are used for speciation, bioavailability, bioaccumulation, persistence, and toxicity were not mentioned nor would one expect this in a summary document of this type. Therefore, it seems inappropriate to make specific recommendations for inclusion of one method over another at this stage, unless a major scientific issue was not addressed in the MAP. In large measure, I felt the MAP covered the essential issues that need to be considered to move the metal assessment plan forward to its next stage of development.

CHARGE QUESTION # 6

6. Please comment on the feasibility of the proposed process for drafting the Framework and the Guidance. Will the timeline allow for the scientific issues to be adequately addressed? Are the measures being taken to involve the scientific community and the public adequate?

Weiss

The response to the question, *What specific steps should be taken to further involve the public and the scientific community in the development of the Framework,* posed by the February, 2002 stakeholder meeting, is one indication of some of the questions needing resolution in this effort. The proposed steps include workshops, *Federal Register* notices, cross-organizational work groups, and a website. But what form should these take? Can these be made more helpful? Only if considerable guidance is provided will any communication efforts prove fruitful.

The first problem that needs to be resolved is the audience for the Framework. The outline states that, "The audience of the framework is primarily risk assessors and the document will also communicate principles of metals assessment to the stakeholders and the public." As a reference source, the content of the proposed Framework should prove extremely useful and comprehensive. The next step, the Guidance document, which presumably will be designed to provide the principles of application, is only superficially described. The close coordination of these two efforts is crucial if they are to prove useful to the Agency.

Consider the task of the risk assessor. The Framework document will present the principles and methods, almost in the form of a textbook of metal toxicology expanded to include regulatory issues. What next? What decisions is the risk assessor then called on to make? Their outlines remain vague, except in general terms. The least desirable outcome of the Framework and Guidance documents would be two processes that fail to intersect properly.

How can the intersection be promoted? Perhaps the most productive approach would be to first determine what the risk assessor will be called on to do and to then formulate a decision process taking the form of a decision tree or a flow chart. The assessor then follows a pathway governed by the need for specific forms of information. For example, "Does the metal exist in more than one chemical form?" If so, the next step might be to follow the sequence for a selected form to questions based on bioaccumulation, duration of persistence, etc. The feasibility of such a decision tree should be considered because, if it proves practical, the Framework document could then be designed along the lines of a programmed text, taking the risk assessor through the process much more

directly than placing the burden on the assessor to select the relevant sections of the Framework.

Adopting such a strategy, namely, structuring the Framework to facilitate the Guidance process, may be more difficult to carry out simply because it requires considerably more deliberation about eventual goals than assigning Agency experts to write specific sections in isolation. The product, however, may eventually prove much more useful and serve as a model for further Agency initiatives. Such a design also would facilitate the kinds of reviews that the Draft Action Plan envisages during the various stages of development. It would invite specific comments about process, the endgame, so to speak, rather than comments on minor technical details.

The schedule laid out in the Draft Action Plan, if the Guidance document is adopted as the basis for the Framework document may require some modification, requiring earlier action on the former rather than on the latter, but the total schedule should not require major revision.

The plans for public and stakeholder involvement and communication seem to be fairly conventional; for example, holding workshops and implementing a Web page. Given the tools now available for promoting communication and imparting information, these plans fall short of the possibilities. The SAB document, *Toward Integrated Environmental Decision-Making*, a product of the Integrated Risk Project, was published in August, 2000 (EPA-SAB-EC-00-011) and is also available in electronic form (http://www.epa.gov/sab/pdf/ecirp011.pdf). Many aspects of that report apply to the Framework and Guidance documents and it is regrettable that the Draft Action Plan failed to make use of its recommendations. One is especially pertinent to the question of public involvement and communication and describes a Web-based survey protocol, devised by the Human Exposure and Health Subcommittee of that project, that could be used to measure and gauge the risk ratings of many different groups. It is available in the full report to the SAB and also described in a scientific publication (Weiss B. A Web-Based Survey Method for Evaluating Different Components of Uncertainty in Relative Health Risk Judgments. Neurotoxicology 22:707-721, 2001.)

Windom

In principle, the proposed process for drafting the Framework and Guidance documents appear appropriate although the component might benefit by a further breakdown and bit more time for consideration. For example, the development of the white papers might benefit from a workshop developed around each of the major scientific issues or groups of them (e.g. speciation/persistence, bioavailability/bioaccumulation/toxicity). This is where the greatest contention will be and it would appear to be a good idea to develop a strong consensus among the various constituencies before organizing the
more general workshop (#1) which puts it all together. Regardless, the schedule appears very ambitious. Is the allocated time sufficient?

Another point has to do with the involvement of other agencies. There is some discussion about this, but it appears to be after the fact. Specifically, the USGS and NOAA are two agencies which have programs regarding metals in the environment. Their experience and data would be useful to the process.

Hayes

The proposed process of getting input from this SAB panel, i.e., white papers drafted on the important issues, and peer consultation workshops is a good format for producing Framework and Guidance Documents. This process allows stakeholders concerns and experiences to be incorporated into the process, and for experts to provide the needed input on the scientific issues to make sure the state of the science is adequate to achieve the goals or to identify where gaps are that need to be addressed so that in the future the result can be achieved.

The timelines appear somewhat tight particularly for developing the white papers by October 2003 for inclusion in the November 2002 peer consultation workshop. Since the quality of the state of science white papers will heavily depend on the "volunteers" how will perform the task, from an academic community standpoint, two months is not very much time to locate the proper individuals, get their commitment, and then have them write the white papers. If "volunteers" have already been located and the white papers are already being written, then this may not be an issue. Success of the timeline presented will essentially be based on getting the white papers in a timely fashion. The succeeding steps in the timeline including interim drafts, SAB review, and final documents (Assessment Framework: Dec 2003; Characterization/Ranking Guidance) should be feasible if the initial parts are performed on time.

CHARGE QUESTION # 7

7. Please comment on the outline for the Framework and the description of the Guidance. Is it clear and all-inclusive?

Pittinger

<u>Framework for Metals Assessment</u>

1. The outline appears to be a synthesis of several EPA Guidelines for Risk Assessment, including both human and ecological dimensions. The "Problem Formulation and Scope of the Analysis", the outline is particularly relevant to the Guidelines for Ecological Risk Assessment.

2. A major concern is that the Framework does not clearly distinguish between hazard and risk, implying that the two are synonymous and can be used interchangeably. The phrase "hazards and risks" are used repeatedly throughout the outline as well as the Draft

Action Plan, as if synonymous. Hazard deals with inherent properties of substances; risk adds the critical exposure element which is necessary to accuracy gauge safety or danger in a given use and exposure scenario. There are several good references which discuss this distinction.

In the introduction, a section is needed which discusses the distinctions between the two. However, beyond adding a section to the Plan Outline, the Agency needs to more broadly and fundamentally rethink where and how hazard and risk differ, and when it is/is not appropriate to use either, and to adapt this perspective throughout the document.

3. A related concern is that Section 1.1.3 "Tiered Approach", attempts to force-fit the tiered approach for risk assessment (and hazard?) into three regulatory functions and processes: the National Hazard/Risk Ranking and Characterization, National Regulatory Assessments, and Site-Specific Assessments. These are in caps as though they are formalized processes, but I'm not aware of guidance or rules which specifically identify them. Will specific guidance documents be developed for each by ORD? Each may include a number of regulatory processes under different statutes and implemented by different Offices or agencies. The tiered risk assessment approach as commonly understood refers to risk assessment and not to hazard assessment.

3. Tiered approaches refer to a systematic development of information, based upon needs for additional accuracy and uncertainty reduction. These proceed from screening level assessments upwards to extensive, in-depth analysis, e.g., clinical studies, mesocosm tests, monitoring, site-specific modeling, metabolite identification and assessment, etc. The outline implies that the 3 regulatory functions categorically follow the tiered risk assessment procedure in the amount and precision of data that will be required to make a decision. Do National Regulatory Assessments always require less data and precision than site-specific assessments? Can't a screening level assessment be performed on a site? Is a National Hazard Characterization (whatever that is) equivalent to a screening level risk assessment?

4. Under Section 4.0, "Characterization of Exposure and Effects", define when and how the risk is calculated. When is the quotient method acceptable versus a distributional, e.g., probabilistic, analysis of risk. When exposure is concerned, this does not concern "hazard", though again the document refers to them synonymously.

5. Section 4.4 "Case Studies", refers to "each regulatory tier", again distorting tiered risk assessment with a concept of tiered regulatory assessment.

6. Section 6.0, and the document in general, seems to overlook the private sector (e.g., companies, trade associations) as a key stakeholder in the assessment process(es) and in coordinating research. Is this intentional?

7. Consider whether separate guidance for solid, aqueous and atmospheric risk assessments are necessary. The methods and concerns for each of these are distinct.

Guidance for Characterization and Ranking of Metals

1. Again there is distortion between hazard and risk. This would seem to be a hazard ranking exercise only. "Risk prioritization" should be done by comparative risk analysis, not by hazard ranking of substances in the absence of exposure context. I am concerned that this exercise will become a generic and overly-simplistic ranking of metals, e.g., Hg, Pb, Cd, Cu, Zn…., without consideration of exposure. This will compromise the risk assessment process and could lead to regulations and practices which are not scientifically sound, if not dangerous. A substance of relatively low toxicity (e.g., a labile surfactant) with relatively high exposure can pose greater risk than a highly toxic but well-managed substance.

2. Will all metals be ranked, including Ca, Mg, Fe, etc., or is a subset of "toxic heavy metals" envisioned? What are the criteria for choosing the subset? How will the Agency distinguish the bimodal effects of essential metals?

3. The first paragraph says it will "address critical needs identified by the stakeholders". Will these include the issues identified by Drs. Luoma and Adams in last weeks call?

4. Can the Panel receive an overview presentation of the "controversy surrounding the recent (lead) decision?

5. If a ranking exercise is completed, it should address uses of metals or context of exposure, e.g.: extraction of minerals; refining; chemical processing and manufacturing; industrial uses as catalysts, etc.; consumer uses, by product sectors; agricultural uses. For each, considerations of intended vs. unintended releases; solid, aqueous and atmospheric releases; re-use and recycling should be addressed.

Other Comments

1. The Executive Summary appears to justify certain parameters for metals assessment on the basis of their use and value in organics assessment. Yet the concepts of persistence and bioaccumulation are wholly different, as we heard last week. I would like to see a discussion of how metals risk assessment is different from organics RA, as well as similarities.

2. The major sections of the document fail to include transport as a major assessment issue, yet this is critical for some metals (e.g., global circulation of atmospheric mercury).

3. The concept of persistence of metals is nonsensical, as all metals are persistent by their nature. Noting this again and again in a risk assessment, e.g., for calcium as well as mercury, adds no value. If chemical speciation, bioavailability and transport are appropriately considered, there is no need to deal with persistence in a metals assessment.

4. The document seems too generic with respect to human vs. ecological risk assessment. How are these different with respect to the treatment of metals?

5. Some statements in the document are over-generalizations: e.g., p. 9, "The greatest consideration of chemical speciation generally occurs in the context of site-specific risk assessments, such as those conducted under the Superfund program."

Costa

The outline seems somewhat redundant and could be made much simpler without any loss of content. I am not sure why regulatory agencies feel that they must be so repetitive maybe it makes them feel more secure about what they are doing who knows.

Anyway if you want me to make it real simple I can do it and I favor that approach. I think the outline uses risk and hazard interchangeably and they are not interchangeable as was pointed out by Pittinger. One of the most important things mentioned is the research to reduce uncertainty. I think maybe metals should be divided into sections according to their major type of hazard ie pb and Hg neurotoxic Ni,As CrVI carcinogenic etc etc

This would help to focus the outline. And make it an interesting and readable document.

I agree with most of Pittinger's comments

Hayes

The outline of the Framework is quite detailed and inclusive. As pointed out in answers to previous charge questions, however, the issue of the impact of metal mixtures needs to be included somewhere in the assessment plan more explicitly. Possible places to include this topic in the outline might be under scientific issue (1.2) and as part of 3.1 Characterization of Exposure either in some of the already covered areas or a separate item under each if the panel feels it should be elevated to that status. The outline as presented currently does not indicate that metal mixtures (and synergism and anatogonism) will not be covered, but in view of the MAP background material provided, it has not so far be incorporated as a major or minor scientific issue to consider.

Another area of concern is the apparent lack of inclusion of a task that directly addresses the issue of what data is available, what data is lacking, and what levels of uncertainty we have for the data that exists. Knowing where improvements in methods will be needed is important if one is to take the state of the science into the metal assessment arena. Although uncertainty analysis is listed as a specific topics in the Framework outline, e.g., under 4.0 Characterization of Exposure and Effects, i.e., 4.3 Uncertainty Analysis, and again as part of 6.0 Research to Reduce Uncertainty, it would also benefit by being included in 3.0 Analysis Phase. An uncertainty and data quality analysis section could be added to the 3.0 Analysis Phase section, where the issues of what methods are available and what data can be reliably obtained could be logically considered.

CHARGE QUESTION # 8

8. Are there any additional actions, beyond those proposed in the Action Plan that could improve EPA's scientific assessments of the hazard and risks of metals?

Friedland & Weiss

A better understanding of synergistic effects of various combinations of metals could improve the assessment of hazard and risk of metals: most MCLs and other metrics of maximum allowable or desired concentrations are evaluated individually. However, in most ecosystems, organisms are affected by a variety of metals simultaneously that are present both naturally and due to anthropogenic activity. The same is true for human beings. In soils, the health of the microbial community is usually measured by the respiration rate. In many cases, the respiration rate is influenced by the sum of metals present rather than by concentrations of individual metals.

AF asked BW: In human beings, is it reasonable to conclude that a similar situation exists?

Response re synergistic effects: Similarly, as noted in the Draft Action Plan, risk assessments for humans must also weigh the possibility of combined effects. As it notes on Page 8, methyl mercury toxicity may be modified by dietary selenium (cf., Watanabe et al, Neurotoxicol Teratol 1999;21:83-88). Other examples are lead toxicity and its modification by dietary calcium and iron. What these examples underscore is that interactions depend, not merely on the amounts of the metals in question or their chemical form, but on their relative quantities, or, put another way, on the balance of metals rather than their sum. If two metals interact biologically, a low level of one combined with a high level of another might promote toxicity, or, conversely, the low level might attenuate the effects of the high level by, say, interfering with absorption.

So perhaps one action to recommend would be a better determination of whether single metal-organism evaluations of toxicity are sufficient in human and mammalian systems and in terrestrial and aquatic systems. Could our issue #8 discussion examine synergistic effects in a broad sense and suggest that interactions between metals must be considered in all systems? And if the answer is yes, how can we establish broadly applicable standards? Is there additional research that needs to be done?

Another issue related to synergistic effects is the effects of metals on stressed systems. Whether the system is a human being suffering malnutrition or disease, or an ecosystem suffering effects of air pollution, global warming or insect infestation, it is probable that effects of metals would be exacerbated by the predisposing agent.

AF asked BW," Do you agree on the human side?"

Response re stressed systems: Impaired function in almost any organ system will predispose that system, and other systems as well, to toxic assaults. When EPA discusses susceptible populations, it often points to the very old or the very young for that reason. Infants have to rely on immature, inadequate mechanisms in certain cases to eliminate chemicals with toxic properties. For example, high nitrate levels in drinking water can pose a special risk for infants because their low stomach acidity facilitates bacterial conversion of nitrate into nitrite and leads to methemoglobinemia. The elderly already are stressed in many instances by existing disease or suboptimal function.

What is the status of human health indicators of metal loading/metal stress? I am aware of Claire Patterson's (CalTech) assertion that all human beings have orders of magnitude more lead than did prehistoric people. I've seen the NHANES studies that I believe present blood lead concentrations in a large cohort of people at different points in time (every 10 years?).

The US Geological Survey has a program called NASQAN (National Stream Quality Accounting Network) that measures chemicals including some metals as well as nutrient ions and pesticides in rivers across the United States (http://water.usgs.gov/nasqan/). The most prominent paper describing this network is Smith et al. 1987 which appeared in Science. There are presently 34 rivers that will be sampled from 2001-2005; the following metals are measured: cadmium chromium, copper, lead, manganese, molybdenum, nickel, silver, zinc, aluminum, uranium. Mercury used to be measured but is no longer (probably because of budget cuts or methodology but I don't know for sure). There used to be many more rivers sampled (hundreds) but that has been reduced (I'm guessing again because of cost). I do not believe there has been a nationwide assessment of metal burdens on natural systems. If I understand the NHANES study correctly, I'm suggesting an analogous study for natural systems: a systematic reporting of the metal concentrations and fluxes at given points in the USA over periodic time intervals.

Re human health indicators and stream concentrations: NHANES does collect lead data, and CDC does as well. We don't have comparable data for other metals. But, as the document notes, it is crucial to recognize that the source of exposure and toxicity may lie several ecological and environmental stages beyond the baseline water concentration. A good example from wildlife is methyl mercury poisoning in Florida panthers. Their source is often raccoons who consume fish from contaminated streams. Similarly, for humans, it is predatory species such as shark and swordfish and sea mammals that present the highest concentrations. This means that a broader ecological assessment is required to determine what a specific metal concentration in a specific waterway might mean to both human health and ecological function.

References Cited:

Smith, R.A., R.B. Alexander and M.G. Wolman. 1987. Water-quality trends in the nation's rivers. Science 235:1607-1615.

Hayes

Answer to Charge Question 7 repeated below.

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